

Benchmarking AIDS

Evaluating Pharmaceutical Company Responses
to the Public Health Crisis in Emerging Markets



ICCR

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to the Public Health Crisis in Emerging Markets

Kieran Hartsough, Public Health Research Associate, ICCR

Daniel E. Rosan, Program Director for Public Health, ICCR

Lisa Sachs, Public Health Research Associate, ICCR

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DISCLAIMER

This report is the result of a long-term collaborative process among investor-members of the Interfaith Center on Corporate Responsibility. The findings, interpretations, and conclusions expressed may not necessarily reflect the views of all the institutional investors involved. The report is intended for informational purposes only. It is not intended to provide, and should not be relied on for, accounting or legal advice, or investment recommendations. We have made every effort to ensure the information provided is reliable, but make no guarantee that it is accurate or complete.

EXECUTIVE SUMMARY

We are facing some of the worst plagues in human history. Over forty million people in the world are living with human immunodeficiency virus (HIV). An estimated six million people need treatment today with antiretroviral drugs or they will soon die, and the remaining millions will require treatment within the next ten years. AIDS currently kills about three million people each year. Tuberculosis, in turn, takes the lives of two million people. An additional three million succumb to malaria. These are deaths that can be avoided, lives that can be extended, and people who can be saved, if we choose to save them.

Providing widespread access to HIV/AIDS treatment can only be done in the context of a broader response to the public health crisis in emerging markets. This crisis includes not only AIDS but also TB, malaria, and other infectious diseases which primarily afflict poor countries. Addressing the crisis requires responsible actions by a number of sectors, only one of which is pharmaceuticals.

Pharmaceutical companies face particular risks for two fundamental reasons: failure to develop new medicines which address diseases of poverty, and poor patients' lack of access to existing medicines. In the first case, the problem is largely market failure. The markets for medicines addressing diseases of poverty are insufficient to give the return today's investors demand. In the second case, the problem is insufficient attention. Today's social contract demands companies take creative, wide-ranging steps to increase access to medicines. Fortunately for pharmaceutical shareholders and patients, neither problem is insurmountable.

Risks to pharmaceutical companies include:

- Risks to the social contract on which drug companies depend to finance innovation and protect intellectual property;
- Risks that emerging markets will withdraw from or undermine international intellectual property agreements;
- Threats to the economic development of emerging markets;
- Risks that rich-country regulatory environments will undermine pricing power in profitable markets;
- Adverse impacts on staff morale and recruitment prospects; and
- A potential inability to successfully secure new markets.

This report will measure how effectively companies are addressing these two fundamental problems by comparing actual pharmaceutical responses against industry best practices. We can conclude that companies whose practices approach best practices are more effectively managing these risks than their peers. The companies addressed in this report include any drug company that controls or produces – or is planning to produce – products which address at least one of the three pandemic diseases, and any other company with global revenues among the top ten in the industry.

Best Practices

We judged each company according to each recommended practice on a five-point scale (5 being highest, 1 lowest). The current status of each practice and the recommended best practices (for which a company would receive a 5) are as follows:

- Research: Fixed-Dose Combinations (FDCs)**
Current Status: Thus far, drug companies have created fixed-dose combinations of antiretrovirals only for pairs of their own products, allowing concerns about brand-share to outweigh undeniable public health benefits of therapeutically appropriate fixed-dose combinations.
Best Practice: Company is taking a leading role in the development or production of FDCs with other companies.
- Research: Neglected Diseases**
Current Status: There has long been an industry-wide neglect of these severe public health threats. There is little market-driven research and development on diseases of poverty, and the available drugs are not universally accessible, are unaffordable to the most affected populations, or are only available in inconvenient or ineffective formulas.
Best Practice: Company has robust programs to research and develop drugs for a range of neglected diseases.
- Pediatric Needs: Formulations**
Current Status: Clinicians treating children with HIV/AIDS have an urgent need for improved formulations, including child-friendly delivery systems such as chewable tablets, smaller pills, and improved syrups that do not require refrigeration.

QUICK REFERENCE CHART																	
Approach	Issue	ABT	AZN	BI	BMJ	GILD	GSK	JNJ	LLY	MRK	NVS	PFE	ROG	SNY	SGP	WYE	Industry Mean
Research	Fixed Dose Combination	2	N/A	1	5	5	2	N/A	N/A	4	N/A	N/A	1	N/A	N/A	N/A	2.9
	Neglected Diseases	1	3	1	1	1	5	4	1	3	5	3	3	5	1	1	2.5
Pediatric Needs	Formulations	3	N/A	2	4	3	3	N/A	N/A	4	N/A	2	4	N/A	N/A	N/A	3.1
	Price Cuts	5	N/A	5	3	1	4	N/A	N/A	3	N/A	N/A	2	N/A	N/A	N/A	3.3
Accessibility	Licensing	1	N/A	3	2	2	4	2	5	2	N/A	1	2	N/A	N/A	N/A	2.4
	Patent Relaxation	1	N/A	1	3	1	1	1	N/A	1	3	1	3	N/A	N/A	N/A	1.6
	Differential Pricing	3	N/A	4	4	4	4	N/A	N/A	5	4	N/A	3	4	N/A	N/A	3.9
	Registration	2	N/A	4	5	2	5	N/A	N/A	2	N/A	N/A	5	N/A	N/A	N/A	3.6
Reporting to Shareholders		3	4	2	3	3	5	4	4	4	4	3	3	4	1	1	3.2
Philanthropy		4	2	3	4	N/A	4	4	4	5	4	3	4	4	N/A	1	3.5
Political Engagement	Political Contributions	2	1	1	2	1	1	4	4	4	1	4	2	3	4	1	2.3
	Trade Association	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1.3

Best Practice: Company produces a range of child-friendly formulations for children in each age group for its entire clinically appropriate product line.

- **Pediatric Needs:** Price Cuts

Current Status: Typically, child formulations are much more expensive than adult formulations.

Best Practice: Pediatric treatment costs per patient per year are equivalent to adult treatment costs.

- **Accessibility:** Licensing & Technology Transfer

Current Status: Voluntary licensing is largely unused by American drug companies. Even when granted, many voluntary licenses are granted to one or two companies only and contain unduly restrictive terms. Many voluntary licenses also lack sufficient technology transfer.

Best Practice: Company has issued three or more non-exclusive licenses for its full range of products, allowing for sales in a wide range of markets. The company provides training and technology to licensees and encourages co-formulation with other brands to develop appropriate fixed-dose combinations.

- **Accessibility:** Patent Enforcement Relaxation

Current Status: Global intellectual property rules are becoming more restrictive, and few companies have relaxed their patents in least developed countries (LDCs) or major generic exporting countries.

Best Practice: The company has no patents in countries that are major generic exporters and no patents in LDCs.

- **Accessibility:** Differential Pricing

Current Status: Most companies have differential pricing schemes only in sub-Saharan Africa, while middle-income nations are regularly excluded from differential pricing schemes or treated on an ad-hoc basis.

Best Practice: Low-income country prices are affordable and predictable. Middle income country prices are affordable and predictable.

- **Accessibility:** Registration

Current Status: Pharmaceutical companies have often failed to obtain registration for all the available dosages and formulations of their products with national drug regulatory agencies in poor countries or have done so on a delayed basis, delaying access to the newest medicines.

Best Practice: Company has obtained registration for all available dosages and formulations in all relevant markets. (We give companies the benefit of the doubt on this topic, and assume registration except where there is specific information available to the contrary.)

- **Reporting To Shareholders:**

Current Status: Many reports tend to be anecdotal, and corporate reporting on HIV/AIDS often focuses solely on philanthropy. Because philanthropic responses are not linked to business strategy and development, reporting on philanthropy does not adequately discuss the business risks of these pandemics nor does it explain how the firm's approach effectively and maximally addresses these risks.

Best Practice: Company's reporting includes an articulation of the business case for action, an assessment of the options for action, systematic reporting of the company's goals and activities, and evidence of leadership at the board level. The report also has pricing schemes and timetables for its access to medicines goals.

- **Sustainable Philanthropy:**

Current Status: Philanthropic programs are the single most popular form of pharmaceutical companies' responses to the HIV/AIDS pandemic. But purely philanthropic responses to the pandemics (gifts of money or products) are not systemic solutions.

Best Practice: Company's philanthropic programs are well integrated into its overall access to medicines programs. They are wide-reaching and sustainable. The programs are built into the company's business strategy and reported to shareholders as such. The activities and impacts of the programs are continuously monitored.

- **Political Engagement:** Political Contributions

Current Status: There is a wide-spread lack of transparency in political contributions in the industry.

Best Practice: Company reports on all political contributions, providing individual rationales for each candidate and group to whom it contributes. The company has board oversight of political contributions.

- **Political Engagement:** Trade Associations

Current Status: Most pharmaceutical firms that choose to participate in trade associations do not report their dues or the political activities which their dues fund.

Best Practice: Company fully discloses its trade association dues and payments to third-party organizations, as well as how those dues are directed. Its dues and payments are consistent with its public position on public health issues. Or, the company is not a member of trade organizations so does not need to report separately on dues.

Key Findings

Our analysis demonstrates that, by and large, pharmaceutical companies are not in compliance with current best practices in responding to HIV/AIDS and neglected diseases. This leads to a number of potential impacts for public health and for institutional investors exposed to the pharmaceutical sector.

KEY FINDINGS		
For Investors	<i>Strategies Vary</i>	Individual responses vary substantially by company: the industry can not be judged monolithically.
	<i>Reporting Is Sub-Standard</i>	Most companies are not reporting on material useful to either shareholders.
	<i>Substantial Risks Remain</i>	Depending on product mix and policies, some companies continue to face substantial downside risks.
	<i>Improve Public Health, Reduce Company Risk</i>	The soundest way to reduce risk is to address, as much as possible, the underlying public health crisis.
For Public Health	<i>Neglected Disease R&D</i>	Some companies are distinguishing themselves, but the majority are taking little action.
	<i>Pediatric AIDS</i>	Children with AIDS continue to have unmet medical needs.
	<i>Second-Line AIDS Drugs</i>	Second-line drugs are less likely to be affordable or available generically.
	<i>AIDS Drug Access Beyond Africa</i>	Company policies are overwhelmingly focused on Africa. Companies may not be prepared to address the spread of AIDS to other regions.

- We found a wide disparity between companies in approaches selected to respond to the public health crisis in emerging markets and in the success of these approaches. Investors would be well served by evaluating responses to the crisis on a company by company basis.
- Almost without exception, we found that company reporting on the public health crisis is poor from an investment value perspective. It appears that the majority of companies are driving their reporting from their public relations or marketing functions. Reporting tends not to contain useful information to make public health judgments. Investors are advised to seek more robust pharmaceutical industry reporting.
- We found little that reassures us that companies are responding adequately to address the industry-wide risks posed by the public health crisis and company-specific regulatory and headline risks.
- The number of public – private partnerships and intensive neglected disease research programs is larger today than it was several years ago. But the range of company responses on this topic is quite wide. Neglected disease R&D may offer companies the greatest opportunity for substantial public health impact. Only a small number of companies appear to recognize this.
- There is an urgent need for pharmaceutical companies to increase resources devoted to making and distributing affordable pediatric AIDS medicines. We found that the gap between best practices and current company practices is wide.
- We found that second-line AIDS drugs continue to be much more expensive and less likely to be licensed or available generically. Additionally, we found that firms have one patent, licensing, and pricing strategy for sub-Saharan Africa and another for the rest of the developing world, thus failing to prepare for the rapid expansion of the AIDS pandemic beyond Africa.



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